DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, Texas 75204 Tel: 214 253-5200	05/03-07/2010 FEI NUMBER 1000117586

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Chinna Pamidi, Ph.D., President

FIRM NAME	STREET ADDRESS
Cetero Research	10550 Rockley Rd., Suite 150
CITY AND STATE *(Zip Code)*	TYPE OF ESTABLISHMENT INSPECTED
Houston TX 77099	Bioanalytical Laboratory

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

This document lists observations made by the FDA representative during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The following observations 1 and 2 pertain to Cetero's internal investigation of complaint allegations initially reported to FDA in June 2009.

1. Falsified source records

Records for the extraction of subject samples in numerous studies were falsified. Specifically, laboratory technicians identified as conducting the work were not present in the facility at the documented time of the study event. Electronic records of card key building entry time indicate that laboratory technicians arrived onsite only after the documented start time of sample extraction in at least 1900 instances over the period of April 15, 2005 through June 30, 2009. The falsification involves data from multiple studies for multiple sponsors.

2. Failure to document procedures for and identity of "prep" run injections

Electronic records of chromatography acquisition for subject sample analysis include a "prep" folder in addition to the study folder of final results. Cetero's internal investigation reported more than (b)(4) "prep" runs for about (b)(4) studies over the period of April 2005 through June 2009. There are no written procedures to describe the selection, evaluation, and reporting of such sample "prep" injections. Aside from the details in the chromatography acquisition software, there is no documentation to confirm the actual identity of the samples saved in the "prep" folder and laboratory staff did not record the injection of "prep" runs in the instrument log book. Cetero's written correspondence to FDA for the "prep" runs does not reveal the lack of written procedures and documentation of the identity of the "prep" injections. Despite the above, the firm's investigation plan claims that the allegation of "fixing" runs to obtain a passing result can be addressed by reviewing the "prep" injections.

3. Study (b)(4) and the two related bioanalytical method validation projects: AP LC/MS/MS 305.100 ((b)(4)) and AP LC/MS/MS 168.100 ((b)(4) (b)(4))

A. Records for the extraction of subject samples for the determination of (b)(4) concentrations in plasma were falsified as described in item 1 above. For Example subject runs 11-16.

B. Records for the extraction of subject samples for the determination of (b)(4) concentrations in plasma were falsified as described in Item 1 above. For Example subject runs 13, 14, 17, and 18.

C. Stability was not demonstrated under the same conditions of study samples. Specifically, stability samples contained either (b)(4) or (b)(4), whereas study samples contained a combination of all (b)(4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Patrick D. Stone, M.S., CSO Jacqueline A. O'Shaughnessy, Ph.D., Pharmacologist Carol M. Rivera-Lopez, Ph.D., Pharmacologist	05/07/2010

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D. Validation documentation was incomplete in that extraction times for some validation runs were not recorded and the storage location of stability samples to demonstrate freeze/thaw and long term stability was not documented.

E. Failed validation runs for projects AP LC/MS/MS 305.100 and AP LC/MS/MS 168.100 were not included in the validation report.

4. Study (b)(4), (b)(4) in Human Plasma

Incomplete documentation for the reinjection of Run 35 for incurred sample reproducibility in that the reinjection report to document the basis for the reinjection was not found in the study file.

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